FDA warns against using COVID-19 at-home test due to bacterial contamination

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(Natural News) The *Food and Drug Administration* (FDA) is advising consumers and healthcare providers to stop using certain lots of recalled SD Biosensor, Inc. Pilot COVID-19 At-Home Tests distributed by Roche Diagnostics.

The product recall is due to significant concerns of bacterial contamination in the Pilot COVID-19 At-Home Test liquid solution provided in the test kit. The FDA warned that direct contact with the contaminated liquid solution may pose safety concerns and that the bacterial contamination could impact the accuracy of the test.

SD Biosensor Pilot COVID-19 At-Home Tests recalled

SD Biosensor, Inc. has initiated a recall for all impacted SD Biosensor Pilot COVID-19 At-Home Tests distributed by Roche Diagnostics to some retailers in America. About 500,000 tests were distributed to CVS Health while about 16,000 tests were distributed to Amazon.

The FDA is working with Roche Diagnostics to confirm how many have been sold to consumers.

The agency noted that none of the impacted lots were distributed through COVID.gov/tests – Free at-home COVID-19 tests, or as part of other federal testing programs.

The FDA is advising consumers to stop using and get rid of Pilot COVID-19 At-Home Test kits with the following lot numbers:

- 53K38N1T1
- 53K38N2T1
- 53K38N3T1
- 53K38N4T1
- 53K38N5T1
- 53K38P1T1
- 53K38P2T1
- 53K38P3T1
- 53K41T5T1
- 53K41X1T1
- 53K41X2T
- 53K41X3T1
- 53K4211T1
- 53K4212T1
- 53K4213T1
- 53K4221T1
- 53K4222T1
- 53K4223T1
- 53K4224T1
- 53K4225T1
- 53K4231T1
- 53K4232T1
- 53K4233T1
- 53K4261T1
- 53K4262T1
- 53K4271T1
- 53K4272T1
- 53K4273T1
- 53K4274T1
- 53K4291T1
- 53K4292T1
- 53K42A1T1

- 53K42A2T1
- 53K42A3T1
- 53K42E1T1
- 53K42G1T1
- 53K42G2T1
- 53K42H1T1
- 53K42H2T1
- 53K42L1T1
- 53K42L2T1
- 53K4361AC
- 53K4362AC
- 53K4392AC

FDA recommendations for consumers, test users and caregivers

Consumers can check if the SD Biosensor Pilot COVID-19 At-Home Test they bought is included in the product recall by verifying the lot number.

Tests confirmed to be contaminated should be thrown out. Do not pour the liquid solution down the drain.

If the liquid in the tube comes into contact with your skin and eyes, flush with large amounts of water. If irritation persists, seek emergency medical attention.

If you or a patient is exposed to the contaminated liquid solution, keep an eye out for signs of bacterial infection. If you notice signs of infection, such as red eyes, discharge, fever or other serious symptoms, seek immediate medical attention.

Talk to your healthcare provider if you suspect that you have been tested with an affected Pilot COVID-19 At-Home Test, or if you have questions or concerns about your test results.

FDA recommendations for healthcare providers and testing program organizers

If the antigen test was performed less than two weeks ago using the Pilot COVID-19 At-Home Test, you might need to retest patients using an FDA-authorized or cleared SARS-CoV-2 diagnostic test to rule out an inaccurate result.

If testing was performed more than two weeks ago and there is no reason to suspect current SARS-CoV-2 infection, there is no need to retest. (Related: FDA unveils plan to combat DEADLY bacterial outbreak in baby formula.)

If a patient experiences signs of bacterial infection, such as conjunctivitis, fever or other signs or symptoms of systemic infection, confirm if they have recently used a Pilot COVID-19 At-Home Test. If the patient used a product with the affected batch number, check if their infection may be from exposure to the contaminated buffer solution.

Report any problems you experience with the Pilot COVID-19 At-Home Test to the FDA, along with suspected false results, through the MedWatch Online Voluntary Reporting Form.

Potential risks of using contaminated Pilot COVID-19 At-Home Test kits

The liquid solution that comes with affected Pilot COVID-19 At-Home Test kits has been found to be contaminated with *Enterococcus*, *Enterobacter*, *Klebsiella* and *Serratia* species.

Using the product on yourself means you may run the risk of direct contact with the contaminated liquid. While the liquid is contained in an individual, ready-to-use, pre-filled and sealed tube, you can accidentally come in direct contact with the contaminated liquid while opening the tube, handling the open tube or performing the test.

The FDA warned that infection with the aforementioned bacteria can cause illness if you have a weakened immune system.

The agency is currently reviewing the SD Biosensor Pilot COVID-19 At-Home Tests recall and classifying the recall risk. The FDA is also working with SD Biosensor Inc. to assess the company's corrective actions to address the reason for bacterial contamination and to help ensure that the situation is resolved and does not happen again.

The FDA will keep the public informed of any new information amid the product recall.

Watch the video below that talks about how the FDA knew COVID-19 vaccines would harm babies.

This video is from The New American channel on *Brighteon.com*.

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Sources include:

FDA.gov

AccessData.FDA.gov

Brighteon.com